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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	19

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,870	FARMER, SEAN	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26, 29, 30 and 33-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 26, 29, 30 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 25, 26, 29, 30 and 33-35 as amended {11/26/2003} are under examination in the instant office action.

Claims 1-24, 27, 28, 31 and 32 are canceled by applicant. {11/26/2003}.

Claim Rejections - 35 USC § 112

New matter

Claim 25 as amended is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation drawn to administration of a generic strain that "produces more lysine aminopeptidase that *Bacillus coagulans* Hammer strain ATCC No. 31284" has no support in the as-filed specification.

The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus that would show possession of the concept of administering a generic strain that "produces more lysine aminopeptidase that *Bacillus coagulans* Hammer strain ATCC No. 31284".

The as-filed specification contains disclosure related to administration of lactic acid producing microorganism belonging to the bacterial species of *Bacillus coagulans* for inhibiting

gastrointestinal infection (see abstract) or for inhibiting vancomycin-resistant *Enterococcus* infection (example on page 66). The specification provides description of some commercially available strains belonging to *Bacillus coagulans* such as, for example: *Bacillus coagulans* Hammer strain ATCC No. 31284 (page 28, par. 2) and other strains that are isolated by applicants (page 37). Although the applicants' strains (identified as isolates GBI-1, GBI-20, GBI-30 and GBI-40) were characterized by aminopeptidase profiles including lysine (page 64, Figures 9-12), the as-filed specification does not indicate that the lysine aminopeptidase activity is related to the method of administration for inhibiting gastrointestinal infection. The enzymatic profiles are established to demonstrate some taxonomic differences on the subspecies level between the strains identified as belonging to *Bacillus coagulans* species but not for the purpose to determine the degree of enzymatic activity (specification page 62, lines 8-11). Moreover, at least some of the applicants' strains (for example: the "20 degree C" isolate) appear to have about the same lysine aminopeptidase profile as the type strain ATCC 31284 (the other name "99% ATCC", see page 6, line 21) as demonstrated on the figures 9 and 12 at number 12 (for lysine aminopeptidase) in terms of fluorescence intensity. Therefore, the lysine aminopeptidase activity is unrelated to the presently claimed method of administration as disclosed in the as-filed specification. The as-filed specification appears to rely on the ability of probiotic bacteria to produce lactic acid and on theirs temperature resistance/tolerance for selecting bacteria suitable in probiotic compositions (page 25, line 19 and page 36, lines 14-21).

Thus, the specification does not provide sufficient support for the new limitation drawn to administration of a generic strain that "produces more lysine aminopeptidase that *Bacillus coagulans* Hammer strain ATCC No. 31284". This is a matter of written description, not a

question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the phrase "produces more lysine aminopeptidase that *Bacillus coagulans* Hammer strain ATCC No. 31284" in the method of administration for inhibiting infection is considered to be the insertion of new matter for the above reasons.

Deposit

Claims 26, 29, 30 and 33-35 as amended are rejected under 35 U.S.C. 112, *first paragraph,* as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to specific microorganisms that are the *Bacillus coagulans* strains GBI-1, GBI-20, GBI-30 and GBI-40. Because the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganisms are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganisms.

The specification does not disclose a repeatable process to obtain the claimed strains and it is not clear from the specification or record that the claimed strains are readily available to the public. For example: the selection of the applicants' strains is based on bacterial spontaneous mutation (specification page 51) and, thus, it is unpredictable. The specification does not indicate

the depository collection for the strains or theirs corresponding accession numbers, for example: the ATCC accession numbers or accession numbers in other culture collection with IDA status.

The rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty in the culture collection having the IDA status and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Please, note that upon proper deposit of the claimed strains, the specification should to be amended to incorporate current address of the depository collection and the corresponding accession numbers for all claimed strains.

Claim Rejections - 35 USC § 102

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection under 35 USC 102 over the references WO/9854982 or US 5,968,569. However, removal of new matter will result in the reinstatement of the art rejection(s).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 26, 29, 30 and 33-35 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO/9854982 or US 5,968,569 taken with the references by Yanagida et al. and by Bergey's Manual.

Claims are directed to a method of inhibiting an infection comprising administering to the gastrointestinal tract of an animal a composition comprising an isolated strain belonging to *Bacillus coagulans*. The claimed strain(s) is a particular strain(s) GBI-1, GBI-20, GBI-30 or/and GBI-40. Some claims are further drawn to the use of viable cells such as vegetative cell or spores, to the use of amounts such as 10^2 - 10^{14} cells or spores per day, to the oral or buccal forms of administration.

The cited documents WO/9854982 or US 5,968,569 taken with the references by Yanagida et al. and by Bergey's Manual are relied upon as explained in the last office action and repeated herein.

The cited documents WO/9854982 or US 5,968,569 are relied for the disclosure of a method of inhibiting an infection comprising administering to the gastrointestinal tract of an animal a composition comprising various representatives of bacterial strains belonging to the species of *Bacillus coagulans* including strain ATCC strain 31284 {WO/9854982} wherein in the method for administration the forms and amounts of compositions are the same as presently claimed. The cited documents teach administration of viable cells including vegetative cells or spores, the use of amounts within the range 10^2 - 10^{14} cells or spores per ml or g of food per day

and the use of oral or buccal forms of administration. For example: see US 5,968,569 at examples 1 and 5; see at col. 6, lines 9-12; see at col. 7 line 49; see at col. 10, line 5656, see at col. 9, line 28. For example: see WO/9854982 at abstract; see page 23, line 3 and line 13; see page 24, line 1; see examples 8-9.

Although the cited documents WO/9854982 or US 5,968,569 do not clearly teach particular *Bacillus coagulans* strains identified as "GBI-1, GBI-20, GBI-30 or/and GBI-40", these documents clearly teach the beneficial effect of administering *Bacillus coagulans* strains for inhibiting gastrointestinal infection in animals. In particular, the cited documents teach the use of generic representative of *Bacillus coagulans* {US 5,968,569} including some particular strain(s) {WO/9854982}.

Although the cited documents are silent with respect to the specific data related to the taxonomic characterization profiles of *Bacillus coagulans*, the other cited references by Yanagida et al. and by Bergey's Manual teach various characteristics of *Bacillus coagulans* bacteria that are relied in the art for strain characterization and taxonomic differentiation between bacterial species and strains as it was explained in the prior office action.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice method of administration of a bacterial composition with *Bacillus coagulans* with a reasonable expectation of success in inhibiting gastrointestinal infection in animals because the similar, if not identical, bacteria belonging to the species of *Bacillus coagulans* have been known, taught and/or suggested in the prior art for the same purpose of inhibiting gastrointestinal infection in animals.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 11/26/2003 have been fully considered but they are not persuasive.

Main applicant's argument is drawn to the idea that the cited prior art does not teach the degree of lysine aminopeptidase activity of the strains as compared to the control strain ATCC 31284. However, this characterization is unrelated to the method of administration of strains as explained above. The method of administration as disclosed in the as-filed specification does not require the use of strains that exhibit some increased amounts of lysine aminopeptidase in order to inhibit gastrointestinal infection. Furthermore, it is also unclear as argued and as disclosed in the specification under what conditions and how much "more lysine aminopeptidase activity than" produced by the strain ATCC 31284 would be sufficient in the method of administration for inhibiting gastrointestinal infection, for example. Moreover, at least some of the applicants' strains (for example: isolate identified as the "20 degree C" isolate) appear to have about the same lysine aminopeptidase profile as the control strain ATCC 31284 (the other name "99% ATCC", see page 6, line 21) as demonstrated on the figures 9 and 12 at number 12 (for lysine aminopeptidase) in terms of fluorescence intensity.

Therefore, Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which applicant thinks the claims present in view of the state of the art disclosed by the references cited or the rejections/objections made. Further, they do not show how the amendments avoid such references or rejections/objections.

Although the applicant's strains might be different from the prior art strain ATCC 31284 (WO 98/54982) with respect to some unidentified characteristics, the criticalities of the differences, if any, in the method for administration are not clearly pointed out by applicant on the record. Moreover, the deposit requirement in not met.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

March 5, 2004

V. Afremova

VERA AFREMOVA

PATENT EXAMINER